

CLAIMS

What is claimed is:

1. A pharmaceutical packaging means for dispensing a single dose
5 of an oxygen-sensitive drug comprising a plurality of unit doses of an oxygen-
sensitive drug, a lid and a blister: wherein each unit dose of said plurality of
unit doses is individually encapsulated between said lid and said blister by
means of a sealable laminate deposited on said lid; and an oxygen absorber is
incorporated into said laminate, said blister, said lid, a layer interposed
10 between said laminate and said lid, or a combination thereof such that said
oxygen absorber removes at least a portion of oxygen from the air surrounding
said oxygen-sensitive drug.
2. The pharmaceutical packaging means of Claim 1 wherein said
15 oxygen absorber is incorporated into said layer interposed between said
laminate and said lid.
3. The pharmaceutical packaging means of Claim 1 wherein said
20 oxygen absorber is incorporated into both said blister and said layer interposed
between said laminate and said lid.
4. The pharmaceutical packaging means of Claim 1, 2 or 3 wherein
25 said oxygen absorber is selected from the group consisting of a moisture-
activated absorber, a self-activated absorber, a UV-activated absorber, an
electron beam activated absorber, a radiation activated absorber, a microwave
activated absorber and combinations thereof.
5. The pharmaceutical packaging means of Claim 4 wherein said
30 oxygen absorber is a moisture-activated absorber selected from the group
consisting of a particulate-type iron, a copper powder, and a zinc powder.
6. The pharmaceutical packaging means of Claim 5 wherein said
oxygen absorber is a particulate-type iron selected from the group consisting

of a hydrogen reduced iron, an electrolytically reduced iron, an atomized iron, and a milled pulverized iron powder.

7. The pharmaceutical packaging means of Claim 1 wherein the
5 oxygen content of the air surrounding said oxygen-sensitive drug is maintained
at a level less than or equal to about 10.0% for about two years.

8. The pharmaceutical packaging means of Claim 1 wherein the
oxygen content of the air surrounding said oxygen-sensitive drug is maintained
10 less than or equal to about 5.0% for about two years.

9 The pharmaceutical packaging means of Claim 1 wherein the
oxygen content of the air surrounding said oxygen-sensitive drug is maintained
at a level less than or equal to about 1.0% for about two years.

15 10. The pharmaceutical packaging means of Claim 1 wherein the
oxygen content of the air surrounding said oxygen-sensitive drug is maintained
at a level less than or equal to about 0.5% for about two years.

20 11. The pharmaceutical packaging means of Claim 1 wherein said
oxygen-sensitive drug comprises a pharmaceutically active ingredient selected
from the group consisting of amines, phenols, sulfides and allylic alcohols.

12. The pharmaceutical packaging means of Claim 1 wherein said
25 oxygen-sensitive drug comprises an oxygen sensitive excipient.

13. The pharmaceutical packaging means of Claim 1 wherein said
oxygen-sensitive drug comprises an oxygen-sensitive pharmaceutically active
compound.

30 14. The pharmaceutical packaging means of Claim 13 wherein said
oxygen-sensitive pharmaceutically active compound is a basic drug having a
pKa value from about 1 to about 10.

15. The pharmaceutical packaging means of Claim 13 wherein said oxygen-sensitive pharmaceutically active compound is a basic drug having a pKa value from about 5 to about 9.

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16. The pharmaceutical packaging means of Claim 13 wherein said oxygen-sensitive pharmaceutically active compound has a redox potential less than or equal to about 1300 mV.

10 17. The pharmaceutical packaging means of Claim 13 wherein said oxygen-sensitive pharmaceutically active compound has a redox potential less than or equal to about 1000 mV.

18. The pharmaceutical packaging means of Claim 13 wherein said oxygen-sensitive pharmaceutically active compound is selected from the group consisting of pseudoephedrine, tiagabine, acitretin, rescinnamine, lovastatin, tretinoin, isotretinoin, simvastatin, ivermectin, verapamil, oxybutynin, hydroxyurea, selegiline, esterified estrogens, tranylcypromine, carbamazepine, ticlopidine, methyldopahydro, chlorothiazide, methyldopa, naproxen, acetominophen, erythromycin, bupropion, rifapentine, penicillamine, mexiletine, verapamil, diltiazem, ibuprofen, cyclosporine, saquinavir, morphine, sertraline, cetirizine, and N-[[2-methoxy-5-(1-methyl)phenyl]methyl]-2-(diphenylmethyl)-1-azabicyclo[2.2.2]octan-3-amine.

25 19. The pharmaceutical packaging means of Claim 1 wherein
degradation or discoloration of said oxygen sensitive drug is reduced by at
least about 20%.

20. The pharmaceutical packaging means of Claim 1 wherein
30 degradation or discoloration of said oxygen sensitive drug is reduced by at least about 50%.

21. The pharmaceutical packaging means of Claim 1 wherein degradation or discoloration of said oxygen sensitive drug is reduced by at least about 75%.

5 22. A process for manufacturing a pharmaceutical packaging means for dispensing a single dose of an oxygen-sensitive drug comprising the steps of:

- 10 (i) providing a blister having a plurality of recesses,
(ii) placing a single unit dose of an oxygen-sensitive drug inside each of said plurality of recesses in said blister, and
(iii) laminating onto said blister from step (ii) a lid comprising a backing having deposited thereon a sealable laminate and a thermoplastic layer containing an oxygen absorber interposed between said backing and said sealable laminate to produce a package containing a plurality of encapsulated single unit doses of said oxygen-sensitive drug.

15 23. The process of Claim 22 wherein said laminating step (iii) is performed in an inert atmosphere.

20 24. The process of Claim 22 wherein said oxygen absorber is selected from the group consisting of a moisture-activated absorber, a self-activated absorber, a UV-activated absorber and combinations thereof.

25 25. The process of Claim 24 wherein said oxygen absorber is a moisture-activated absorber selected from the group consisting of a particulate-type iron, a copper powder, and a zinc powder.

30 26. The process of Claim 25 wherein said oxygen absorber is a particulate-type iron selected from the group consisting of a hydrogen reduced iron, an electrolytically reduced iron, an atomized iron, and a milled pulverized iron powder.

27. The process of Claim 22 wherein said oxygen-sensitive drug comprises a pharmaceutically active ingredient selected from the group consisting of amines, phenols, sulfides and allylic alcohols.

5 28 The process of Claim 22 wherein said oxygen-sensitive drug comprises an oxygen sensitive excipient.

29. The process of Claim 22 wherein said oxygen-sensitive drug comprises an oxygen-sensitive pharmaceutically active compound.

10 30. The process of Claim 29 wherein said oxygen-sensitive pharmaceutically active compound is a basic drug having a pKa value from about 1 to about 10.

15 31. The process of Claim 29 wherein said oxygen-sensitive pharmaceutically active compound is a basic drug having a pKa value from about 5 to about 9.

20 32. The process of Claim 29 wherein said oxygen-sensitive pharmaceutically active compound has a redox potential less than or equal to about 1300 mV.

25 33. The process of Claim 29 wherein said oxygen-sensitive pharmaceutically active compound has a redox potential less than or equal to about 1000 mV.

34. The process of Claim 29 wherein said oxygen-sensitive pharmaceutically active compound is selected from the group consisting of pseudoephedrine, tiagabine, acitretin, rescinnamine, lovastatin, tretinooin, 30 isotretinooin, simvastatin, ivermectin, verapamil, oxybutynin, hydroxyurea, selegiline, esterified estrogens, tranylcypromine, carbamazepine, ticlopidine, methyldopahydro, chlorothiazide, methyldopa, naproxen, acetominophen, erythromycin, bupropion, rifapentine, penicillamine, mexiletine, verapamil,

diltiazem, ibuprofen, cyclosporine, saquinavir, morphine, sertraline, cetirizine, and N-[[2-methoxy-5-(1-methyl)phenyl]methyl]-2-(diphenylmethyl)-1-azabicyclo[2.2.2]octan-3-amine.